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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1709

MAIL DATE

DELIVERY MODE

05/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/777,581	Applicant(s) KLEIN ET AL.	
	Examiner Bobby Ramdhanie, Ph.D.	Art Unit 1709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
 4a) Of the above claim(s) 32-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date
:02/11/2004,05/27/2004,09/24/2004,05/15/2006,06/13/2006,.

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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-31 are drawn to a well plate, classified in class 422, subclass 102.
 - II. Claims 32-49 are drawn to an apparatus to be used with the well plate of Group I, classified in class 435, subclass 4.
 - III. Claims 50-56 are drawn to another apparatus to be used with the well plate of Group I, classified in class 435, subclass 4.
2. IV. Claims 56-61 are drawn to a method of using the plurality of detectors in the well plate of Group I, classified in class 422, subclass 102.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to

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petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. During a telephone conversation with Mr. Halbert on 04/30/07 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-31. Affirmation of this election must be made by applicant in replying to this Office action. Claims 32-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claim 1-14, 19, 20, 22, 23, and 25-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rao (US 2002/0025547 A1). Regarding Claim 1, Rao teaches a well plate comprising a plurality of wells, each well being defined by at least one surface that defines a cavity having an opening, wherein each well comprises at least one aperture through the at least one surface of the well, the aperture configured to provide a gas supply access to the interior of the well; and at least one of a pH level sensor and dissolved oxygen sensor disposed within the well (Figures 1 and 2).
3. For Claim 2, Rao teaches the well plate of Claim 1 wherein each well is defined by a bottom surface and at least one side surface that defines the opening (Figure 1).
4. For Claim 3, Rao teaches the well plate of Claim 1 wherein the at least one of a pH level sensor and a dissolved oxygen sensor (Figure 1) comprises a fluorescent material ([0096]) disposed on the interior of that at least one surface of the well.
5. For Claim 4, Rao teaches the well plate of Claim 3 wherein the at least one of a pH level sensor and a dissolved oxygen sensor are disposed on the interior of the bottom surface of the well (Figure 6).
6. For Claim 5, Rao teaches the well plate of Claim 1, wherein at least one of a pH level sensor and a dissolved oxygen sensor comprise at least one probe that is coupled to the interior of the well (Figure 3b, [0096]).
7. For Claim 6, Rao teaches the well plate of Claim 5, further comprising a lid configured to be placed over the plurality of wells, wherein the at least one probe extends from the lid into the interior of the well (Figure 2).

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8. For Claim 7, Rao teaches the well plate of Claim 1, further comprising at least one membrane coupled to the at least one surface of each well and covering the at least one aperture (Figure 2, [0097]).

9. For Claim 8, Rao teaches the well plate of Claim 7 wherein each well is defined by a bottom surface and at least one side surface and the at least one membrane is coupled to the bottom surface of each well ([0097] and Figure 6).

10. For Claim 9, Rao teaches the well plate of Claim 7 wherein the membrane is formed from a gas permeable material ([0057]). Examiner takes the position that the ACRO 50 0.2 μm PTFE filter is the gas permeable material.

11. For Claim 10, Rao teaches the well plate of Claim 7 wherein the membrane is formed from porous material with pores less than 0.2 μm ([0057]).

12. For Claim 11, Rao teaches the well plate of Claim 7 wherein a plurality of membranes is used with each well. (Figure 6).

13. For Claim 12, Rao teaches the well plate of Claim 1 wherein each well comprises a plurality of apertures through the at least one surface of the well, the plurality of apertures configured to provide a gas supply to the interior of the well (Figure 2).

14. For Claim 13, Rao teaches the well plate of Claim 1 wherein each well comprises an array of apertures through the at least one surface of the well, the array the plurality of apertures configured to provide a gas supply to the interior of the well, wherein each aperture in the array is approximately 0.2 mm to 1 mm in diameter (Figure 2, and [0127]).

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15. For Claim 14, Rao teaches the well plate of Claim 1, wherein each well further comprises a second aperture through the at least one surface of the well, the second aperture configured to place a temperature control element in thermal contact with the interior of the well, and a third aperture through the at least one surface of the well, the third aperture configured to place a temperature measurement element in thermal contact with the interior of the well ([0068], [0012], [0112], [0113], [0115]).

16. For Claim 19, Rao teaches a well plate comprising a plurality of wells ([0068], [0012]), each having at least one surface that defines an opening at the top of the well, wherein each well comprises a first aperture through the at least one surface of the well, the first aperture configured to provide a gas supply ([0127]) access to the interior of the well, and at least one additional aperture through the at least one surface of the well, the at least one additional aperture through the at least one additional aperture configured ([0011-0012]) to place one of a temperature control element ([0113]) and a temperature measurement element ([0115]) in thermal contact with the interior of the well.

17. For Claim 20, Rao teaches the well plate of Claim 19 ([0068], [0012], [0127]) wherein the at least one additional aperture through the at least one surface of the well comprising with the second aperture through one of the surfaces of the well, second aperture configured to place a temperature measurement element in thermal contact with the interior of the well ([0013]), and a third aperture through one of the surfaces of the well the third aperture configured to place a temperature control element in thermal contact with the interior of the well ([0115]). Figure 6 shows the well with a pH and

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oxygen sensor chemical films on the bottom of the well. Rao also teaches that the temperature sensor can be a film and placed on the bottom of the well. All three of these films sit on top of an aperture of the well.

18. For Claim 22, Rao teaches the well plate according to Claim 19, wherein the first aperture is one of a plurality of apertures through at least one surface of the well that are configured to provide a gas supply access to the interior of the well (Figure 2, [0011-0012], [0013], and [0015]).

19. For Claim 23, Rao teaches the well plate of Claim 22, wherein the plurality of apertures form an array of apertures, wherein each aperture in the array is approximately 0.2 to 1 mm in diameter (Figure 2, [0127]). Examiner takes the position that 0.25 mm is within the specified 0.2 – 1 mm diameter range.

20. For Claim 25, Rao teaches the well plate in Claim 19. Rao also teaches the means for sensing at least one of the pH level and dissolved oxygen within the well ([0106]).

21. For Claim 26, Rao teaches the well plate of 25, wherein the means for sensing comprises one or more fluorescent materials disposed on the bottom interior surface of the well (Figure 6, [0096]).

22. For Claim 27, Rao teaches the well plate of Claim 25, wherein the means for sensing comprises at least one probe that extends into the interior of each well ([0104]).

23. For Claim 28, Rao teaches the well plate of Claim 27. Rao also teaches the well plate further comprising a lid configured to be placed over the wells wherein, the at least one probe extends from the lid into the interior of the well (Figure 8).

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24. For Claim 29, Rao teaches the well plate of Claim 19, further comprising at least one membrane coupled to the at least one surface of each well and covering the at least one aperture (Figure 2 and Figure 3b).

25. For Claim 30, Rao teaches the well plate of Claim 19, a first membrane coupled to at least one surface of each well (Figure 1) and covering the at least one aperture and a second membrane coupled to the at least one surface of each well and covering at least one of the second and third apertures (Figure 1).

Claim Rejections - 35 USC § 103

26. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

27. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

28. Claims 15-17, 21, 24, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao (US 2002/0025547 A1) in further in view of Olivier (US

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2003/0219360 A1). Regarding Claim 15, Rao teaches the well plate of Claim 1 wherein at least one surface of each well has a first thickness (Figure 1, [0029]). Rao however, does not teach the indentation having a second thickness that is less than the first thickness. Olivier teaches a well plate having an indentation having a second thickness that is less than the first thickness (Figure 7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rao with Olivier because the design of the microtiter plate in Olivier would allow for the microtiter plate to be in SBS format and allow for a multistack bioreactor to be created ([0017]).

29. For Claim 16, Rao teaches the use of a well plate in accord with Claim 15. Rao does not teach a well plate having an indentation with a second thickness. Olivier teaches a well plate with the second thickness (Figure 7) which further comprises a thermally conductive material (Olivier, [0020]) within the indentation. It would have been obvious to one skilled in the ordinary art at the time the invention was made to modify Rao with Olivier because the thermally conductive material would allow for more efficient thermal energy transfer between bioreactor and the bioreactor platform (Rao, [0120]).

30. For Claim 17, Rao teaches a first membrane coupled to at least one surface of each well (Figure 3b) and covering the at least one aperture and a second membrane coupled to the at least one surface of each well and covering at least one of the second and third apertures (Figure 2). Rao however, does not teach the indentations on the surface of the well to provide a different thickness. Olivier teaches this feature (Figure 7). It would have been obvious to one skilled in the ordinary art to modify Rao with

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Olivier because the well plate in Olivier is commonly available as a standard plate and is made in compliance with SBS format.

31. For Claim 21, Rao teaches the well plate of Claim 19. Rao does not teach at least one additional aperture through a bottom surface of each well. Olivier teaches a well plate that possesses the at least one additional aperture through a bottom surface of each well (Figure 7). It would have been obvious to one skilled in the ordinary art to modify Rao in view of Olivier because the drain at the bottom of each well would allow fluid in the well to escape and drain into a collection plate ([0025]).

32. For Claim 24, Rao teaches the well plate in Claim 19. Rao does not teach the well plate wherein the first aperture comprises a plurality of supporting ribs extending across the first aperture. Olivier teaches a plurality of support ribs extending across the first aperture (Figure 6). It would have been obvious to modify Rao in view of Olivier because the design of Olivier would allow for structural support upon use of a vacuum to remove liquid from the well.

33. Claims 18 & 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao (US 2002/0025547 A1) and in further in view of Olivier (US 2003/0219360 A1), Rao (Rao, 1994), and Wolfbeis (Wolfbeis, 1995)., Rao teaches the well plate of Claim 1 wherein at least one surface of each well has a first thickness ([0029]), the well plate of Claim 15 containing the two sensors of Rao et al, 1994 and Wolfbeis et al, 1995. Rao does not teach the indentation having a second thickness that is less than the first thickness and a membrane having a first thickness over the at least one aperture and

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having a second thickness over the second and third apertures. Olivier teaches a well plate having an indentation having a second thickness that is greater than the first thickness (Figure 7). Olivier also teaches a membrane that covers the third aperture at the bottom of the well. The thickness of one sensor has been found to be 0.5 mm (Rao et al 1994, p. 1141) the thickness of a second sensor has been made to be 2-4 μm (Wolfbeis et al 1995, p. 136). Both sensors sit upon apertures of the bottom of the well. Heat-sealing the membrane on the bottom of the well causes the filter material to soften or melt and fuse together forming an integral fluid tight seal ([0021]). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rao with Olivier because the design of the well plate in Olivier would allow for the membrane to be on the bottom of the well to be used to separate the fluid from the solid material after a reaction had been completed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 571-272-1447. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR


WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER